

Claims

What is claimed is:

1. A fenofibrate composition comprising granulates, wherein the granulates comprise micronized fenofibrate, inert carrier particles, at least one hydrophilic polymer and at least one surfactant, wherein the weight ratio of micronized fenofibrate to hydrophilic polymer is between 1:10 and 4:1.
2. The composition of claim 1, wherein the weight ratio of fenofibrate/hydrophilic polymer is between 1/2 and 2/1.
3. The composition of claim 1, wherein the fenofibrate has a size less than 20 μm .
4. The composition of claim 1, wherein the fenofibrate has a size less than 10 μm .
5. The composition of claim 1, wherein the inert carrier particles are inert hydrosoluble carrier particles.
6. The composition of claim 1, wherein the inert carrier particles have a particle size between 50 and 500 microns.
7. The composition of claim 1, wherein the inert carrier particles have a particle size between 100 and 400 microns.
8. The composition of claim 1, wherein the hydrophilic polymer is a polyvinylpyrrolidone, a poly(vinyl alcohol), a hydroxypropylcellulose, a hydroxymethylcellulose, a hydroxypropylmethylcellulose, a gelatin, or a mixture of two or more thereof.
9. The composition of claim 1, wherein the hydrophilic polymer is a polyvinylpyrrolidone.
10. The composition of claim 1, wherein the surfactant is sodium lauryl sulfate, monooleate, monolaurate, monopalmitate, monostearate or another ester of polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearlyc alcohol, cetostearyl alcohol, cholesterol, polyoxyethylene ricin oil, polyoxyethylene fatty acid glycerides, poloxamer, or a mixture of two or more thereof.
11. The composition of claim 1, wherein the surfactant is sodium lauryl sulfate.
12. The composition of claim 1, wherein the weight ratio of surfactant to hydrophilic polymer is from 1/500 to 1/10.
13. The composition of claim 1, wherein the weight ratio of surfactant to hydrophilic polymer is from 1/100 to 5/100.

14. The composition of claim 1, wherein the granulates comprise, based on the weight of the granules, from 5 to 50% by weight of fenofibrate, from 10 to 75% by weight of carrier, from 20 to 60% by weight of hydrophilic polymer, and up to 10% by weight of surfactant.

5 15. The composition of claim 1, wherein the granulates comprise, based on the weight of the granules, from 20 to 45% by weight of fenofibrate, from 20 to 50% by weight of carrier, from 25 to 45% by weight of hydrophilic polymer, and from 0.1 to 3% by weight of surfactant.

10 16. A fenofibrate composition comprising granulates, wherein the granulates comprise micronized fenofibrate, inert carrier particles, at least one hydrophilic polymer and at least one disintegrant, wherein the weight ratio of micronized fenofibrate to hydrophilic polymer is between 1:10 and 4:1.

17. The composition of claim 16, wherein the weight ratio of fenofibrate/hydrophilic polymer is between 1/2 and 2/1.

15 18. The composition of claim 16, wherein the fenofibrate has a size less than 20 µm.

19. The composition of claim 16, wherein the fenofibrate has a size less than 10 µm.

20 20. The composition of claim 16, wherein the inert carrier particles are inert hydrosoluble carrier particles.

21. The composition of claim 16, wherein the inert carrier particles have a particle size between 50 and 500 microns.

22. The composition of claim 16, wherein the inert carrier particles have a particle size between 100 and 400 microns.

23. The composition of claim 16, wherein the hydrophilic polymer is a polyvinylpyrrolidone, a poly(vinyl alcohol), a hydroxypropylcellulose, a hydroxy-25 methylcellulose, a hydroxypropylmethylcellulose, a gelatin, or a mixture of two or more thereof.

24. The composition of claim 16, wherein the hydrophilic polymer is a polyvinylpyrrolidone.

25. The composition of claim 16, wherein the at least one disintegrating agent is selected from the group consisting of starch, colloidal silica, cross-linked polyvinyl pyrrolidone 30 and carboxymethyl starch, and a mixture of two or more thereof.

26. The composition of claim 16, wherein the granulates further comprise at least one surfactant.
27. The composition of claim 26, wherein the surfactant is sodium lauryl sulfate, monooleate, monolaurate, monopalmitate, monostearate or another ester of polyoxyethylene 5 sorbitane, sodium dioctylsulfosuccinate, lecithin, stearlylic alcohol, cetostearyllic alcohol, cholesterol, polyoxyethylene ricin oil, polyoxyethylene fatty acid glycerides, poloxamer, or a mixture of two or more thereof.
28. The composition of claim 26, wherein the surfactant is sodium lauryl sulfate, monooleate, monolaurate, monopalmitate, monostearate or another ester of polyoxyethylene 10 sorbitane, sodium dioctylsulfosuccinate, lecithin, stearlylic alcohol, cetostearyllic alcohol, cholesterol, polyoxyethylene ricin oil, polyoxyethylene fatty acid glycerides, poloxamer, or a mixture of two or more thereof.
29. The composition of claim 26, wherein the surfactant is sodium lauryl sulfate.
30. The composition of claim 26, wherein the weight ratio of surfactant to 15 hydrophilic polymer is from 1/500 to 1/10.
31. The composition of claim 26, wherein the weight ratio of surfactant to hydrophilic polymer is from 1/100 to 5/100.
32. The composition of claim 16, wherein the granulates comprise, based on the weight of the granules, from 5 to 50% by weight of fenofibrate, from 10 to 75% by weight of 20 carrier, and from 20 to 60% by weight of hydrophilic polymer.
33. The composition of claim 16, wherein the granulates comprise, based on the weight of the granules, from 20 to 45% by weight of fenofibrate, from 20 to 50% by weight of carrier, and from 25 to 45% by weight of hydrophilic polymer.
34. The composition of claim 32, wherein the granulates comprise, based on the 25 weight of the granules, up to 10% by weight of surfactant.
35. The composition of claim 33, wherein the granulates comprise, based on the weight of the granules, from 0.1 to 3% by weight of surfactant.
36. A fenofibrate composition comprising granulates and at least one disintegrant, wherein the granulates comprise micronized fenofibrate, inert carrier particles and at least one 30 hydrophilic polymer, wherein the weight ratio of micronized fenofibrate to hydrophilic polymer is between 1:10 and 4:1.

37. The composition of claim 36, wherein the weight ratio of fenofibrate/hydrophilic polymer is between 1/2 and 2/1.
38. The composition of claim 36, wherein the fenofibrate has a size less than 20 μm .
39. The composition of claim 36, wherein the fenofibrate has a size less than 10 μm .
- 5 40. The composition of claim 36, wherein the inert carrier particles are inert hydrosoluble carrier particles.
41. The composition of claim 36, wherein the inert carrier particles have a particle size between 50 and 500 microns.
- 10 42. The composition of claim 36, wherein the inert carrier particles have a particle size between 100 and 400 microns.
43. The composition of claim 36, wherein the hydrophilic polymer is a polyvinylpyrrolidone, a poly(vinyl alcohol), a hydroxypropylcellulose, a hydroxymethylcellulose, a hydroxypropylmethylcellulose, a gelatin, or a mixture of two or more thereof.
- 15 44. The composition of claim 36, wherein the hydrophilic polymer is a polyvinylpyrrolidone.
45. The composition of claim 36, wherein the at least one disintegrating agent is selected from the group consisting of starch, colloidal silica, cross-linked polyvinyl pyrrolidone and carboxymethyl starch, and a mixture of two or more thereof.
- 20 46. The composition of claim 36, wherein the granulates further comprise at least one surfactant.
47. The composition of claim 36, wherein the surfactant is sodium lauryl sulfate, monooleate, monolaurate, monopalmitate, monostearate or another ester of polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearlylic alcohol, cetostearyl alcohol, cholesterol, polyoxyethylene ricin oil, polyoxyethylene fatty acid glycerides, poloxamer, or a mixture of two or more thereof.
- 25 48. The composition of claim 46, wherein the surfactant is sodium lauryl sulfate, monooleate, monolaurate, monopalmitate, monostearate or another ester of polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearlylic alcohol, cetostearyl alcohol, cholesterol, polyoxyethylene ricin oil, polyoxyethylene fatty acid glycerides, poloxamer, or a mixture of two or more thereof.
- 30 49. The composition of claim 46, wherein the surfactant is sodium lauryl sulfate.

50. The composition of claim 46, wherein the weight ratio of surfactant to hydrophilic polymer is from 1/500 to 1/10.

51. The composition of claim 46, wherein the weight ratio of surfactant to hydrophilic polymer is from 1/100 to 5/100.

5 52. The composition of claim 36, wherein the granulates comprise, based on the weight of the granules, from 5 to 50% by weight of fenofibrate, from 10 to 75% by weight of carrier, and from 20 to 60% by weight of hydrophilic polymer.

10 53. The composition of claim 36, wherein the granulates comprise, based on the weight of the granules, from 20 to 45% by weight of fenofibrate, from 20 to 50% by weight of carrier, and from 25 to 45% by weight of hydrophilic polymer.

54. The composition of claim 52, wherein the granulates comprise, based on the weight of the granules, up to 10% by weight of surfactant.

55. The composition of claim 53, wherein the granulates comprise, based on the weight of the granules, from 0.1 to 3% by weight of surfactant.

15 56. A fenofibrate composition comprising granulates, wherein the granulates comprise micronized fenofibrate, inert carrier particles, at least one hydrophilic polymer, at least one surfactant, wherein the weight ratio of micronized fenofibrate to hydrophilic polymer is between 1:10 and 4:1 and the weight ratio of surfactant/hydrophilic polymer is between 1/500 and 1/10.

20 57. The composition of claim 56, wherein the weight ratio of fenofibrate/hydrophilic polymer is between 1/2 and 2/1.

58. The composition of claim 56, wherein the fenofibrate has a size less than 20 μm .

59. The composition of claim 56, wherein the fenofibrate has a size less than 10 μm .

25 60. The composition of claim 56, wherein the inert carrier particles are inert hydrosoluble carrier particles.

61. The composition of claim 56, wherein the inert carrier particles have a particle size between 50 and 500 microns.

62. The composition of claim 56, wherein the inert carrier particles have a particle size between 100 and 400 microns.

63. The composition of claim 56, wherein the hydrophilic polymer is a polyvinylpyrrolidone, a poly(vinyl alcohol), a hydroxypropylcellulose, a hydroxymethylcellulose, a hydroxypropylmethylcellulose, a gelatin, or a mixture of two or more thereof.

64. The composition of claim 56, wherein the hydrophilic polymer is a
5 polyvinylpyrrolidone.

65. The composition of claim 56, wherein the surfactant is sodium lauryl sulfate, monooleate, monolaurate, monopalmitate, monostearate or another ester of polyoxyethylene sorbitane, sodium dioctylsulfosuccinate, lecithin, stearlylic alcohol, cetostearyllic alcohol, cholesterol, polyoxyethylene ricin oil, polyoxyethylene fatty acid glycerides, poloxamer, or a
10 mixture of two or more thereof.

66. The composition of claim 56, wherein the surfactant is sodium lauryl sulfate.

67. The composition of claim 56, wherein the weight ratio of surfactant to hydrophilic polymer is from 1/100 to 5/100.

68. The composition of claim 56, wherein the granulates comprise, based on the
15 weight of the granules, from 5 to 50% by weight of fenofibrate, from 10 to 75% by weight of carrier, from 20 to 60% by weight of hydrophilic polymer, and up to 10% by weight of surfactant.

69. The composition of claim 56, wherein the granulates comprise, based on the weight of the granules, from 20 to 45% by weight of fenofibrate, from 20 to 50% by weight of
20 carrier, from 25 to 45% by weight of hydrophilic polymer, and from 0.1 to 3% by weight of surfactant.

70. A fenofibrate composition comprising granulates, wherein the granulates
comprise micronized fenofibrate, inert carrier particles, polyvinylpyrrolidone, sodium lauryl sulfate, wherein the weight ratio of micronized fenofibrate to polyvinylpyrrolidone is between
25 1:10 and 4:1 and the weight ratio of sodium lauryl sulfate/polyvinylpyrrolidone is between 1/500 and 1/10.

71. The composition of claim 70, wherein the weight ratio of
fenofibrate/polyvinylpyrrolidone is between 1/2 and 2/1.

72. The composition of claim 70, wherein the fenofibrate has a size less than 20 μm .

30 73. The composition of claim 70, wherein the fenofibrate has a size less than 10 μm .

74. The composition of claim 70, wherein the inert carrier particles are inert hydrosoluble carrier particles.
75. The composition of claim 70, wherein the inert carrier particles have a particle size between 50 and 500 microns.
- 5 76. The composition of claim 70, wherein the inert carrier particles have a particle size between 100 and 400 microns.
77. The composition of claim 70, wherein the weight ratio of sodium lauryl sulfate to polyvinylpyrrolidone is from 1/100 to 5/100.
- 10 78. The composition of claim 70, wherein the granulates comprise, based on the weight of the granules, from 5 to 50% by weight of fenofibrate, from 10 to 75% by weight of carrier, from 20 to 60% by weight of polyvinylpyrrolidone, and up to 10% by weight of sodium lauryl sulfate.
- 15 79. The composition of claim 70, wherein the granulates comprise, based on the weight of the granules, from 20 to 45% by weight of fenofibrate, from 20 to 50% by weight of carrier, from 25 to 45% by weight of polyvinylpyrrolidone polymer, and from 0.1 to 3% by weight of sodium lauryl sulfate.
80. The composition of claim 1, wherein the fenofibrate is in a non-reagglomerated form.
- 20 81. The composition of claim 16, wherein the fenofibrate is in a non-reagglomerated form.
82. The composition of claim 36, wherein the fenofibrate is in a non-reagglomerated form.
- 25 83. The composition of claim 56, wherein the fenofibrate is in a non-reagglomerated form.
84. The composition of claim 70, wherein the fenofibrate is in a non-reagglomerated form.